

Henry E. Schwartz LLC  
901 Dulaney Valley Road, Suite 400  
Towson, MD 21204  
Phone: 410.938.8703 / Fax: 410.823.6017  
henryeschwartzllc@verizon.net

January 26, 2004

**VIA COURIER**

Dockets Management Branch (HFA-305)  
Food and Drug Administration, Room 1051  
5630 Fishers Lane  
Rockville, MD 20852

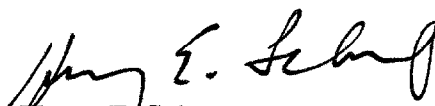
RE: In re: Korangy Radiology Associates, P.A., et al.  
FDA Docket No. 2003H-0432

Dear Sir/Madam:

Enclosed for filing in the above-referenced matter please find an original and one copy of Respondents' Request for Protective Order.

Thank you for your attention to this filing. Please contact me with any questions.

Sincerely,

  
Henry E. Schwartz

Enclosure

cc: Amile Korangy, M.D.  
Douglas A. Terry, Esquire

2003H-0432

G:\files\HSchwartz\Balt Imaging Ctr\courrier 1-26-04.DOC

MD2

2003 04 JAN 26 12:18

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 26 12:20

In the Matter of:

KORANGY RADIOLOGY ASSOCIATES,  
P.A., t/a BALTIMORE IMAGING  
CENTERS,

\* ADMINISTRATIVE COMPLAINT  
FOR CIVIL MONEY PENALTY

\*

FDA Docket: 2003H-0432

And

\*

AMILE A. KORANGY, M.D.

\* \* \* \* \*

RESPONDENTS' REQUEST FOR PROTECTIVE ORDER

Respondents, by their undersigned attorneys, having received Complainant's First Request for Production of Documents, hereby seek protection from several of the specific requests contained therein, on the bases that these requests are not relevant to the issues under appeal (21 CFR 17.23(a)), are unduly costly or burdensome (21 CFR 17.23(d)(2) and 21 CFR 17.28), seek privileged information (21 CFR 17.23(d)(3) and 21 CFR 17.28), and constitute an unwarranted invasion of personal privacy (21 CFR 17.28).

The specific requests herein objected to, and the specific reasons for such objections, follow:

1. Request #1(i) relates to all official corporate acts, with no limitation as to subject matter or timeframe. Any such request should be limited as to relevancy (have one or more relevant subjects) and to timeframe. Otherwise, it reflects an abusive, overbroad and irrelevant request that also encompasses confidential commercial information.

2. Request #1(iii) relates to all financial records of Respondents as well as any entity in any unspecified way related to Respondents. This request is an abusive, expensive, overly broad and burdensome request that also seeks confidential commercial information and violates personal privacy. Further, it relates to parties uninvolved in any way in the instant case. Again, there is no limitation with respect to subject or timeframe, guaranteeing the irrelevancy of the request to any issues contained in the instant case. Complainant has no legitimate interest in any financial records of the Respondents, let alone in having produced all financial records developed at any point during the lifetime of any party to this case and their business associates.

3. Request #2 seeks any document "reflecting" any asset of Respondents and their families. The assets of Respondents are not relevant to the issues in the instant case. The assets of family members are less so. The request contains no limitation regarding scope or timeframe, and is overbroad, burdensome, and constitutes an unwarranted invasion of personal privacy.

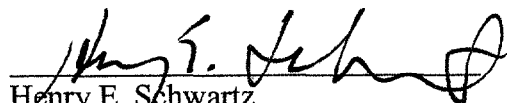
4. Request #3 seeks any document "relating to" all financial transactions between Respondents, without limitation as to scope, subject or timeframe. This request addresses no issue in the instant case, and is overbroad, unduly burdensome and costly, and constitutes an unwarranted invasion of personal privacy and the production of confidential commercial information.

5. Request #4 seeks all documents "relating to" the annual receipts and number of employees of Respondents, as well as any entities unrelated to the instant case in which Respondents may exercise ownership or control interests, or in which Respondents' relatives may hold ownership interests. This request contains no limitations as to scope, subject matter or timeframe. This request addresses no issue in the instant case, and is overbroad, unduly burdensome and costly, and constitutes an unwarranted invasion of personal privacy and the production of confidential commercial information.

6. Request #7 seeks, in part, all documents evidencing communications between Amile A. Korangy, M.D., Barry J. Henderson, and Irfam S. Shafique, M.D. This request contains no limitation as to scope, subject matter or timeframe, and is therefore overbroad, unduly burdensome and costly, and constitutes an unwarranted invasion of personal privacy and the production of confidential commercial information. Such a request should be limited as to relevancy to issues in the instant case and as to timeframe.

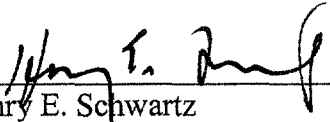
For the foregoing reasons, Respondents respectfully request that a Protective Order be issued, limiting Complainant's Document Production Request to items relevant as to issue and timeframe.

Respectfully Submitted;

  
Henry E. Schwartz  
Henry E. Schwartz LLC  
901 Dulaney Valley Road, Suite 400  
Towson, MD 21204  
410. 938.8703  
[henryeschwartzllc@verizon.net](mailto:henryeschwartzllc@verizon.net)

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 26 day of January, 2004, a copy of the foregoing Respondents' Request for Protective Order was mailed, postage prepaid, to Douglas A. Terry, Esquire, Office of the General Counsel, Food and Drug Administration, 5600 Fishers Lane, GCF-1, Rockville, MD 20857.

  
Henry E. Schwartz